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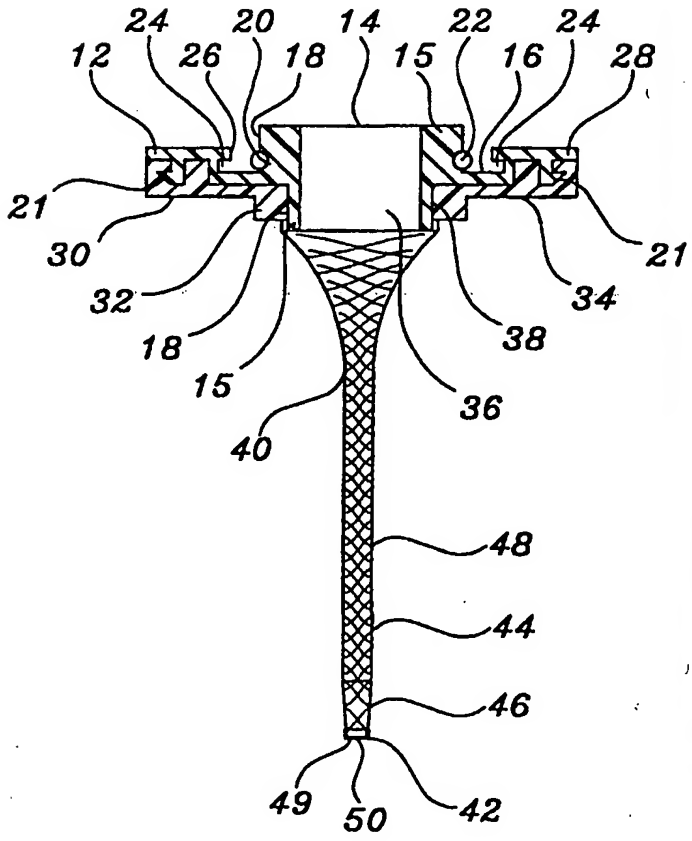
(54) Title: COATED RADIALLY EXPANDABLE DILATOR FOR USE WITH GASTROINTESTINAL–TYPE TUBES

(57) Abstract

A device for use in placing specialized gastrointestinal–type tubes (200) within the abdomen of a patient having a lubricant coating (44) thereon for improved preformance.



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COATED RADIALLY EXPANDABLE DILATOR FOR USE WITH GASTROINTESTINAL-TYPE TUBES

Technical Field

The present invention relates to a device for use in placing gastrointestinal-type tubes within the abdomen or intestine of a patient and more particularly to a coated radially expandable dilator having greater rigidity and less friction for improved insertion capabilities when used to place enteral access devices or laproscopic instruments within the abdomen or intestine of a patient.

Background Art

Modern medicine frequently requires percutaneous access to hollow body organs, tissue, cavities, and the like. In the case of "least or minimally invasive" surgical procedures, such access is usually provided by inserting a suitable cannula, instrument, tube, or the like, through a small access hole. The initial access is usually created by piercing the skin and any intermediate body structures with a needle or trocar. The initial puncture, however, is usually very small so that the needle or trocar can achieve the desired penetration without excessive damage to tissue. It is therefore necessary for the initial access hole to be subsequently enlarged to provide a working channel having a sufficient diameter to permit performance of the desired medical procedure and access with the desired instruments and/or tubing.

One common technique for achieving such enlargement relies on successively introducing one or more dilating

rods having increasingly larger diameters through the puncture hole and into the body organ, tissue, or cavity. When a flexible guide wire has been introduced through the initial needle or cannula puncture, this protocol is referred to as the Seldinger technique.

While this technique is reasonably effective for placement of relatively small devices, e.g., catheters to about 6 French (0.079 inch or 2mm in diameter), larger dilations require increasing numbers of dilator exchanges and can be extremely time consuming. Moreover, the body structures that are being penetrated frequently comprise relatively flaccid membranes or walls so that penetration with larger dilators may cause fascial detachment, i.e., the invagination and separation of the membrane or wall from surrounding tissue structures. Such problems may be exacerbated when the organ, tissue, or cavity being penetrated is diseased so that the membranes or walls are thickened or toughened and resistant to penetration by the dilator which axially engages the tissue.

An additional problem with the use of successively larger dilators is the leakage of body fluids and like substances through the penetration site which is being enlarged. Although such leakage will be inhibited while each successive dilator is in place, removal of the dilator will allow the fluids from the organ, tissue or cavity being penetrated to contaminate other body structures on the puncture track. For example, percutaneous access to the gallbladder is normally achieved transperitoneally since the gallbladder is partially attached to the liver. Transperitoneal access proceeds through an unattached wall

of the gallbladder and increases the likelihood of bile leakage into the peritoneal. While transperitoneal access might otherwise be preferred for a number of reasons, e.g., it avoids potential damage to the liver, it is contraindicated due to the difficulty in penetrating the unattached wall of the gallbladder and the greater risk of bile leakage associated therewith than with conventional dilator techniques.

For these reasons, it would be desirable to provide improved methods and apparatus for forming enlarging percutaneous penetrations into hollow body organs, tissues, and cavities. The apparatus and methods should be suitable for enlarging percutaneous access penetrations to virtually any diameter, including very large diameters on the order of 20 French, 24 French, (.262 inch or 6.67mm and .314 inch or 8mm in diameter, respectively) and larger while reducing the risk of invagination and fascial detachment of the organ, tissue, or cavity which is being penetrated. The methods should minimize any additional time and complexity required for performing an associated interventional procedure, and in particular, should avoid the need to make secondary penetrations in order to secure the body organ, tissue, or cavity to surrounding fascia. The methods should further avoid complexity and will preferably reduce the number of incremental dilations required to achieve a desired enlargement. The method should also lessen the patient discomfort associated with the procedure and should be compatible with virtually any type of interventional procedure which requires the formation of a percutaneous penetration for access to the body organ, tissue, or cavity.

Disclosure of Invention

The present invention provides a coated radially expandable dilator for use in placement of specialized gastrointestinal-type tubes. Specifically, the instant invention provides a safer, easier to use, more comfortable means for placing a specialized gastrointestinal-type tube using a coated radially expandable dilator. The coated radially expandable dilator of the present invention comprises a housing, gripping means extended outwardly from the housing, an aperture extending through the housing between the gripping means, an elongated tubular sleeve member attached within the aperture so as to extend therefrom and a coating on the elongated tubular sleeve member.

The coated radially expandable dilator of the present invention is used in conjunction with a needle device wherein a needle device is insertable through the aperture and elongated tubular sleeve member of the dilator so as to allow a hollow needle portion and optionally a tubular sheath portion thereof to extend outwardly from said elongated tubular sleeve member.

The coated radially expandable dilator of the present invention is also capable of being used in conjunction with the specialized gastrointestinal-type tube of the present invention wherein a gastrointestinal-type tube attached to a slenderized bolster is insertable through the aperture and elongated tubular sleeve member of the dilator so as to allow the bolster to extend outwardly from the elongated tubular sleeve member.

One such specialized gastrointestinal-type tube which can be used in conjunction with the coated radially expandable dilator includes a tube which comprises a length of elastomeric tubing with opposed ends, a first of said opposed ends attached to an internal retention bolster, an obturator stick removably attached within the bolster so as to extend through the tubing and extend beyond the second of the opposed ends. Attachment means are located on the second of the opposed ends and an obturator stick locking device is removably attached to the attachment means for locking the obturator stick in a position to maintain the bolster in a slenderized state.

The obturator stick locking device comprises a body portion having opposed ends, attachment means extending from one of the opposed ends, a finger grip portion attached to a second of the opposed ends and one or more tooth members extending from the finger grip portion or from the body portion to allow the obturator stick to be locked below the finger grip portion near the attachment means.

A method of placing a gastrointestinal-type tube using the coated radially expandable dilator device (10) of the present invention comprises inserting the radially expandable dilator device (10) having a needle device inserted therethrough and locked therein through the abdomen of a warm-blooded animal or human and into a specified organ, removing the needle device from the radially expandable dilator device (10), optionally inserting a trocar device which includes a trocar member and channel member through the radially expandable dilator device (10) and removing the trocar member, inserting a

gastrointestinal-type tube through the channel member if used within the radially expandable dilator device (10) to expose a bolster portion of the tube within the organ, releasing pressure from the obturator stick of the tube to enlarge the bolster and removing the channel member and radially expandable dilator device (10) from the organ and abdomen as described in detail below.

Accordingly, it is a primary objective of the instant invention to provide a coated radially expandable dilator for more easily and reliably placing gastrointestinal-type tubes. It is a further object to provide an easily manipulated specialized gastrointestinal-type tube and modified obturator stick locking device.

Other objects, features and advantages of the invention shall become apparent in view of the description when considered in connection with the accompanying illustrative drawings.

Brief Description of Drawings

In the drawings which illustrate the best mode presently contemplated for carrying out the present invention:

Figure 1 is a plan view of the coated radially expandable device of the present invention;

Figure 2 is a top elevational view of the device of Figure 1;

Figure 3 is a bottom elevational view of the device of Figure 1;

Figure 4 is a plan view of the needle device used in conjunction with the device of Figure 1;

Figure 5 is a plan view of the modified gastrointestinal-type tube used in conjunction with the device of Figure 1 with the bolster in a slenderized state;

Figure 6 is a plan view of the modified gastrointestinal-type tube of Figure 5 with the bolster in an enlarged state; and

Figure 7 is a top elevational view of a two-part skin disc used in conjunction with the modified gastrointestinal-type tube of Figure 5 and Figure 6 illustrated in an open position;

Figure 8 is a plan view of a unitary skin disc used in conjunction with the modified gastrointestinal-type tube of Figure 5 and Figure 6;

Figure 9 is a cross-sectional view of Figure 1 cut along line 9--9;

Figure 10 is a cross-sectional view of Figure 4 cut along line 10--10;

Figure 11 is a plan view of the trocar device optionally used in conjunction with the device of Figure 1;

Figure 12 is a plan view of the trocar member of the device of Figure 11; and

Figure 13 is a plan view of the channel member of the device of Figure 11; and

Figure 14 is a magnified partial plan view of the device of Figure 1 taken at a point along line 14--14.

Description of the Invention

Referring to the drawings, an embodiment of the coated radially expandable dilator device (10) of the present

invention is illustrated and generally indicated as 10 in Figures 1 through 3, 9, and 14.

The coated radially expandable dilator device (10) 10 comprises a rigid planar top placement portion 12 having an aperture 14 formed therethrough defined by aperture wall 15. Around said aperture wall 15 is an annular channel 16. On an exterior wall 18 of aperture wall 15 within channel 16 is a slight groove 20 in which an O-ring 22 is placed. At one or more points around channel 16, planar top surface 28 extends beyond channel exterior wall 24 of channel 16 thus creating at least one notch 26. The aperture wall 15 may or may not extend above or beyond the planar top surface 28 of top place placement portion 12.

Top placement portion 12 is attached to planar bottom placement portion 30 to form housing 31 by any suitable attachment means 21 such as but not limited to one or more means selected from the group consisting of male/female threaded means, friction fit, interlocking means and adhesive. Bottom placement portion 30 has an annular ridge 32 extending outwardly from the bottom surface 34 thereof. Inside annular ridge 32 is aperture 36. Upon attachment of top placement portion 12 with bottom placement portion 30, with attachment means 21 the aperture external wall 18 of aperture wall 15 is in direct communication with the interior wall 38 which defines aperture 36. External wall 18 may extend outwardly beyond annular ridge 32. Extending from between interior wall 38 and external wall 18 is an elongated braided and/or woven tubular sleeve member 40 made up of woven filaments 46 and sheathing film 48 which extends to form an aperture 50 at a free end 47 thereof. Aperture 50

is in fluid communication with aperture 14. Elongated woven tubular sleeve member 40 may or may not have a smooth covering 42. Coating smooth covering 42 or if no smooth covering 42 is present, coating sleeve member 40 is a coating layer 44. Coating layer 44 may be constructed by applying low friction materials such as Teflon® (Dupont); polyethylene; one or more hydrophilic polymers such as polyvinyl alcohol, polyarylic acid and its derivatives such as polyacrylamide, polysaccharide, polyvinylpyrrolidone or polyoxyethylene; one or more hydrophilic polymer blends such as polyvinylpyrrolidone-polyurethane blend or poly(n-vinyl lactom)-polyurethane blend; one or more hydrophilic polymers or polymer blends as described above combined with a primer such as aldehyde, epoxy or isocyanate; grafting to the device surface one or more hydrophilic unsaturated monomers such as an acrylamide or acrylic acid and its derivatives; or one or more interpenetrating polymer network such as polyoxyethylene with polyisocyanate, polyvinylpyrrolidone with polyisocyanate, polyvinylpyrrolidone with cellulose or its derivatives such as nitrocellulose, polypropylene glycol or its derivatives with polyisocyanate, polyethylene glycol or its derivatives with carboxyl and/or cellulose groups or polyethylene glycol or its derivatives with isocyanate and/or cellulose groups. Preferably coating layer 44 is made up of one or more hydrophilic polymers. Polyvinylpyrrolidone has been found to be the preferred hydrophilic polymer for coating layer 44 due to its proven biocompatibility. Coating layer 44 provides a significant improvement to such a dilator device (10) 10 because it significantly reduces the coefficient of friction while adding rigidity to the sleeve

member 40 by temporarily bonding the woven filaments 46 of sleeve member 40 as best illustrated in Figure 14. Sleeve member 40 is made up of woven filaments 46 covered with sheathing film 48 and optionally smooth covering 42. Preferably smooth covering 42 is eliminated with the use of coating layer 44 since smooth covering 42 often times creates a "buckling" or "bunching" problem upon use of device 10. It is unexpected that the coating layer 44 would be suitable to replace smooth covering 42 and eliminate the problems associated therewith due to the belief that coating layer 44 would be insufficient to provide the requisite rigidity. However, coating layer 44 as described above is a lubricant layer which has been found to provide the requisite rigidity and allow for easier placement of the radially expansible dilator while reducing or eliminating "buckling" or "bunching" of smooth covering 42.

Needle device 100 illustrated in Figures 4 and 10 is made up of an elongated hollow needle 102 having two opposed ends 103 and 105. Adjacent to free closed end 103 is an opening 104 in fluid communication with interior portion 106 thereof. Opening 104 is adjacent to closed end 103 rather than through closed end 103 to protect opening 104 from tissue blockage. Hollow needle 102 is inserted through a tubular member 108. Tubular member 108 has two opposed ends 109 and 110. Hollow needle 102 protrudes through free open end 110 of tubular member 108 so as to expose opening 104. Tubular member 108 at open end 110 is cut at an oblique angle 122 so as to create a sharpened tip 112 to aid in insertion. Hollow needle 102 is spring loaded as described below so as to be retractable within tubular member 108.

Both tubular member 108 and hollow needle 102 are attached by ends opposed to ends 103 and 110, i.e., 105 and 109 respectively, to housing member 114. Housing member 114 is tubular in shape having opposed top aperture 116 and bottom aperture 118. Top aperture 116 is sized to accept tubing or a variety of standardized medical device adaptors such as for example stopcock 117, and bottom aperture 118 is sized to accept tubular member 108 and hollow needle 102. Hollow needle 102 is spring loaded by means of spring 120 housed within housing member 114. Housing member 114 is likewise equipped with at least one outwardly extending tab member 124.

Gastrointestinal-type tubing device 200 illustrated in Figures 5 and 6 is made up of elongated elastomeric tubing 202 having opposed top end 204 and bottom end 206. Bottom end 206 is securely attached to bolster 208 by means of annular edge 210 of tube means 212. Opposite annular edge 210 on tube means 212 is free annular edge 214. Approximately midway between annular edge 210 and free annular edge 214 of tube means 212 is attached annular flange 216. Attached to tube means 212 just below the attachment of annular flange 216 and just above free annular edge 214 are a plurality of bowed arms 218. Arms 218 extend outwardly from tube means 212 in a convex manner to be then joined by ends 224 to form a tip 220. Tip 220 has an aperture 228 therein. Support members 226 are formed below arms 218 on tube means 212 to add support to bowed arms 218. Extending from tip 220 through aperture 228, through tube means 212 through tubing 202 and through top end 204 is obturator stick 231 with an end cap 254. Top end 204 is

split 228 to form two tube extensions 230 and 232. Tube extensions 230 and 232 are perforated 215 or similarly altered to allow for the attachment of insert or removal device 234. Insert or removal device 234 has a body portion 236 having two opposed ends 238 and 240. Opposed end 240 of device 234 has one or more attachment means or pegs 252 to attach each tube extension 230 and 232. Opposed end 238 of body portion 236 is attached to finger grip portion 242. Approximately in the middle of finger grip portion 242 is groove 244 having at least one tooth member 250 extending therefrom in the direction of said tubing 202.

Trocar device 300 illustrated in Figures 11 through 13 is made up of a trocar member 302 and channel member 303. Trocar member 302 includes a solid trocar housing 304 and a solid distally tapered trocar 306. The solid tapered trocar 306 has a rounded free tip 308. Extending from trocar housing 304 is a means of attachment 310. Means of attachment 310 works in combination with attachment means 311 on channel housing 314 to create a seal between the two members. Such attachment means of 310 and 311 can be selected from the group consisting of male and female interlocking means, threaded means and/or friction fit. Channel housing 314 of channel member 303 is equipped with a channel aperture 312 formed therethrough. Permanently formed or attached within channel aperture 312 is tapered tubular extension 316 having an opening 318 at free end 320. Upon attaching trocar housing 304 to channel housing 314 by means of attachment means 310 and 311, trocar 306 extends through tubular extension 316 and rounded free tip 308 extends out of channel opening 318 beyond free end 320.

Skin disc device 400 illustrated in Figure 7 is a relatively flat disk shaped device designed to have an aperture 402 through the body portion 404 thereof. The body portion 404 may be made up of two portions 410 and 412 attached by a hinge member 406. Accordingly, hinge member 406 allows the body portion 404 to be spread apart in an open fashion as illustrated in Figure 7. Likewise body portion 404 may be snapped closed with interacting locking means 414 and 416 on portions 410 and 412 respectively to form a ring. Optionally, within aperture 402 there may be a plurality of teeth members 408 for grasping the elastomeric tubing 202 of device 200 although not preferred. Alternatively, skin disk device 400 may be a unitary device as illustrated in Figure 8, which slips around elastomeric tubing 202 of device 200 to maintain tubing 202 in place by means of a high friction coefficient.

In order to use the above described devices 10, 100, 200 and optionally 300 and 400 to place a gastrointestinal-type tube device 200 through the abdominal wall into the peritoneal cavity and into a specified organ of a warm-blooded animal or human, the hollow needle 102 of device 100 is inserted through aperture 14 of device 10 until it is exposed and extending from open end 50 of sleeve member 40. Tab member 124 of device 100 may then be slipped within channel 16 and rotated within notch 26 so as to lock device 100 within device 10.

Hollow needle 102 is then pressed against the abdominal wall causing hollow needle 102 to retract within tubular member 108 to expose sharpened tip 112. Tip 112 passes through the abdomen wall and into the interior cavity of the

organ of choice, e.g., the stomach. Tab member 124 is then rotated from within notch 26 and needle device 100 is removed from device 10.

Optionally, trocar device 300 is inserted through device 10 while device 10 is in the interior cavity of the organ of choice to enlarge the diameter of tubular sleeve member 40. To insert device 300 through device 10, rounded free tip 308 is placed within aperture 14 and pressure is applied on trocar housing 304 in the direction of the abdomen until channel housing 314 abuts top aperture 14. Upon channel housing 314 abutting top aperture 14, rounded free tip 308 and channel opening 318 extends outwardly from tubular sleeve member 40 beyond open end 50. Means of attachment 310 is then released from attachment means 311 and trocar member 302 is removed from channel housing 314. Tip 220 of device 200 is then inserted through channel aperture 312 of channel housing 314 until slenderized bolster 208 is passed completely through channel opening 318 and free end 320 and open end 50 of tubular sleeve member 40. In order to pass bolster 208 through channel opening 318, obturator stick 231 may optionally be locked by tooth member 250 extending from finger grip portion 242 by placing end cap 254 beneath tooth member 250. This ensures that bolster 208 is in a slenderized state as illustrated in Figure 5. If one chooses to not lock obturator stick 231 with tooth member 250, the bolster 208 may be held in a slenderized state by applying a force on obturator stick 231 with ones thumb. Once the bolster 208 is passed completely through channel opening 318, obturator stick 231 is unlocked from tooth member 250 relieving pressure therefrom and is

allowed to extend beyond finger grip portion 242 as illustrated in Figure 6. By releasing the pressure from end cap 254 and obturator stick 231 in such a manner, bolster 208 expands. Tube extensions 230 and 232 are then removed from attachment means or pegs 252 of insert or removal device 234 to remove device 234. The obturator stick may then be removed from device 200 by applying an extraction force thereon away from the abdomen. A force is then applied on housing 31 to remove device 10 and channel housing 314 from the abdomen and from around tubing 202, thus leaving only device 200 in place. Force is then optionally placed on tubing 202 a direction away from the abdomen to pull the organ of choice into communication with the interior abdomen wall. A skin disc device 400 as illustrated in Figures 7 and 8 is then placed around tubing 202 so as to be in contact with the abdomen. Preferably an unitary type skin disc device 400 is used (Figure 8), however, should a two-part device be used (Figure 7), it is snapped closed and locked by attachment means 414 and 416, so as to lock around tubing 202. Movement thereof is then prevented by friction or optionally although not preferred a plurality of teeth members 408 (Figure 7). Once the unitary or two-part skin disc is in place against the abdomen, pressure may be released from tubing 202.

If trocar device 300 is not utilized as just described, tip 220 of device 200 is inserted through aperture 14 of device 10 until the bolster 208 is passed completely through open end 50 of sleeve member 40. In order to pass bolster 208 through open end 50, obturator stick 231 optionally may be locked by one or more tooth members 250 extending from

finger grip portion 242. This ensures that bolster 208 is in a slenderized state as illustrated in Figure 5. Once the bolster 208 is passed completely through open end 50, obturator stick 231 is unlocked from tooth member 250 relieving pressure therefrom and is allowed to extend beyond finger grip portion 242 as illustrated in Figure 6. By releasing the pressure from obturator stick 231 in such a manner, bolster 208 expands. Tube extensions 230 and 232 are then removed from attachment means or pegs 252 of insert or removal device 234 to remove device 234. The obturator stick may then be removed from device 200 by applying an extraction force thereon away from the abdomen. A force is then applied on housing 31 to remove device 10 from the abdomen and from around tubing 202, thus leaving only device 200 in place. Force is then optionally placed on tubing 202 a direction away from the abdomen to pull the organ of choice into communication with the interior abdomen wall. A skin disc device 400 as illustrated in Figures 7 and 8 is then placed around tubing 202 so as to be in contact with the abdomen as described above. Pressure may then be released from tubing 202. Likewise, device 200 may be placed within the abdomen of a warm-blooded animal or human through the use of an existing stoma tract.

To remove device 200 from the abdomen, a skin disc device 400, if present, is removed and extensions 230 and 232 are attached to pegs 252 of device 234. An obturator stick 231 is slid through tubing 202 into bolster 208. Obturator stick 231 may optionally be locked into position below finger grip portion 242 by means of end cap 254 and tooth member 250 as described above. With the obturator

stick 231 locked into position in such a manner bolster 208 is in its slenderized state. A force is then exerted on finger grip portion 242 in a direction away from the abdomen to remove said device from the organ and abdomen.

Devices 10, 100, 200, 300 and 400 may be formed from any suitable material such as for example with rigid parts, suitable metals, synthetic polymers, or a combination thereof, and for example with expandable elastomeric portions, natural rubber, synthetic rubber, synthetic polymers, combinations thereof or the like.

The preferred dimensions of devices 10, 100 and 300 preferably are the same or similar to those articles already known in the art. Device 200 is preferably dimensioned to be at least six inches in length but preferably eight to fifteen inches having a tubing diameter of 10 to 24 French but preferably 16 French. Device 400 is dimensioned to have an aperture approximately the same as that of the tubing, i.e., 10 to 24 French but preferably 16 French.

It is seen therefore that the present invention provides an effective gastrointestinal-type tube placement device utilizing a coated radially expandable dilator device (10) which has specific advantages over the devices and methods heretofore known. The devices and methods disclosed herein eliminate risks associated with the placement of internal retention bolsters within the abdomen. Such a risk now eliminated includes the accidental expansion of retention bolsters intra-peritoneal before being fully inserted in the desired location. The present device likewise allows for re-slenderization of the internal retention bolster before removal thereof and lessens the

tissue damage normally associated with such tube placement. The device also provides more comfort for the patient. Hence, for these reasons as well as others some of which hereinabove set forth, it is seen that the invention represents a significant advancement which has substantial commercial significance.

While there is shown and described herein certain specific embodiments of the invention, it will be manifest to those skilled in the art that various modifications may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.

Claims

1. A gastrointestinal-type tube placement device (10) including a radially expandable dilator device (10) comprising a housing (31), gripping means (28) extended outwardly from said housing (31), and aperture (14) extending through said housing (31) between said gripping means (28), an elongated tubular sleeve member (40) attached within said aperture (14) so as to extend therefrom and a lubricant coating (44) said elongated tubular sleeve member (40) to increase the rigidity and decrease the coefficient of friction thereof.

2. The gastrointestinal-type tube placement device (10) of claim 1 wherein said lubricant (44) is selected from the group consisting of Teflon®, polyethylene, one or more hydrophilic polymers, one or more hydrophilic unsaturated monomers, one or more hydrophilic polymer blends, one or more hydrophilic polymers or polymer blends in combination with a primer and one or more interpenetrating polymer networks.

3. The gastrointestinal-type tube placement device (10) of claim 1 wherein said lubricant (44) is selected from the group consisting of polyvinylpyrrolidone, polyoxyethylene, polyacrylic acid and its derivatives, polyvinyl alcohol, polyvinylpyrrolidone-polyurethane, poly(n-vinyl lactom)-polyurethane, polysaccharide, polyvinylpyrrolidone with isocyanate, polyvinylpyrrolidone with cellulose groups and polyvinylpyrrolidone with isocyanate and cellulose groups.

4. The gastrointestinal-type tube placement device (10) of claim 1 wherein a gastrointestinal-type tube (200) attached to a slenderized bolster (208) is insertable through said aperture (14) and said elongated tubular sleeve (40) member so as to allow said bolster (208) to extend outwardly from said elongated tubular sleeve member (40).

5. The gastrointestinal-type tube placement device (10) of claim 1 wherein a needle device (100) is insertable through said aperture (14) and said elongated tubular sleeve (40) member so as to allow a hollow needle portion (102) and optionally a tubular sheath portion (108) thereof to extend outwardly from said elongated tubular sleeve member (40).

6. A gastrointestinal-type tube (200) comprising a length of elastomeric tubing (202) with opposed ends (204, 206), a first of said opposed ends (206) attached to an internal retention bolster (208), an obturator stick (231) removably attached within said bolster (208) so as to extend through said tubing (202) and extend beyond a second of said opposed ends (204), attachment means (215) located on said second of said opposed ends (204) and an obturator stick locking device (234) removably attached to said attachment means (215) for locking said obturator stick (231) in a position to maintain said bolster (208) in a slenderized state.

7. The gastrointestinal-type tube (200) of claim 6 wherein said attachment means (215) include one or more perforations in said tube (202) to allow for removable

attachment to pegs (252) located on said obturator stick locking device (234).

8. The gastrointestinal-type tube (200) of claim 6 wherein said obturator stick locking device (234) locks said obturator stick (231) by means of one or more tooth members (250).

9. The gastrointestinal-type tube (200) of claim 6 wherein said obturator stick locking device (234) includes a body portion (236), opposed ends of said body portion (238, 240), attachment means (252) extending from one of said opposed ends (240), a finger grip portion (242) attached to a second of said opposed ends (238), and one or more tooth members (250) extending from said finger grip portion (242) to allow an obturator stick (231) to be locked below said finger grip portion (242) near said attachment means (252).

10. A method of placing within an abdomen of a warm-blooded animal or human a gastrointestinal-type tube (200) using ~~the gastrointestinal-type~~ tube placement device (10) of claim 1 comprising inserting said placement device (10) having a needle device (100) inserted therethrough and locked therein through an abdomen and into a specified organ, removing said needle device (100) from said placement device (10);

inserting a gastrointestinal-type tube (200) through said placement device (10) to expose a bolster portion (208) of said gastrointestinal-type tube (200) within said organ;

releasing pressure from an obturator stick (231) removably attached within said bolster (208) to enlarge said bolster (208);

removing said placement device (10) from said abdomen and organ.

11. A method of placing within an abdomen of a warm-blooded animal or human a gastrointestinal-type tube (200) of claim 6 comprising inserting said tube (200) through a stoma or a coated placement device (10) to expose a bolster portion (208) of said gastrointestinal-type tube (200) within the abdomen;

releasing pressure from an obturator stick (231) removably attached within said bolster (208) to enlarge said bolster (208), and if used;

removing said coated placement device (10) from said abdomen.

12. A method of removing from an abdomen of a warm-blooded animal or human a gastrointestinal-type tube (200) using the gastrointestinal-type tube placement device (10) of claim 1 comprising,

inserting an obturator stick (231) through a gastrointestinal-type tube (200) into a bolster portion (208) of said gastrointestinal-type tube (200) within said organ;

applying force to said obturator stick (231) removably attached within said bolster (208) to slenderize said bolster (208);

removing said gastrointestinal-type tube (200) with attached slenderized bolster (208) from said abdomen and organ.

13. A method of removing from an abdomen of a warm-blooded animal or human a gastrointestinal-type tube (200) of claim 6 comprising;

inserting an obturator stick (231) through a gastrointestinal-type tube (200) into a bolster portion (208) of said gastrointestinal-type tube (200) within said organ;

apply force to said an obturator stick (231) removably attached within said bolster (208) to slenderize said bolster (208);

removing said gastrointestinal-type tube (200) with attached slenderized bolster (208) from said abdomen.

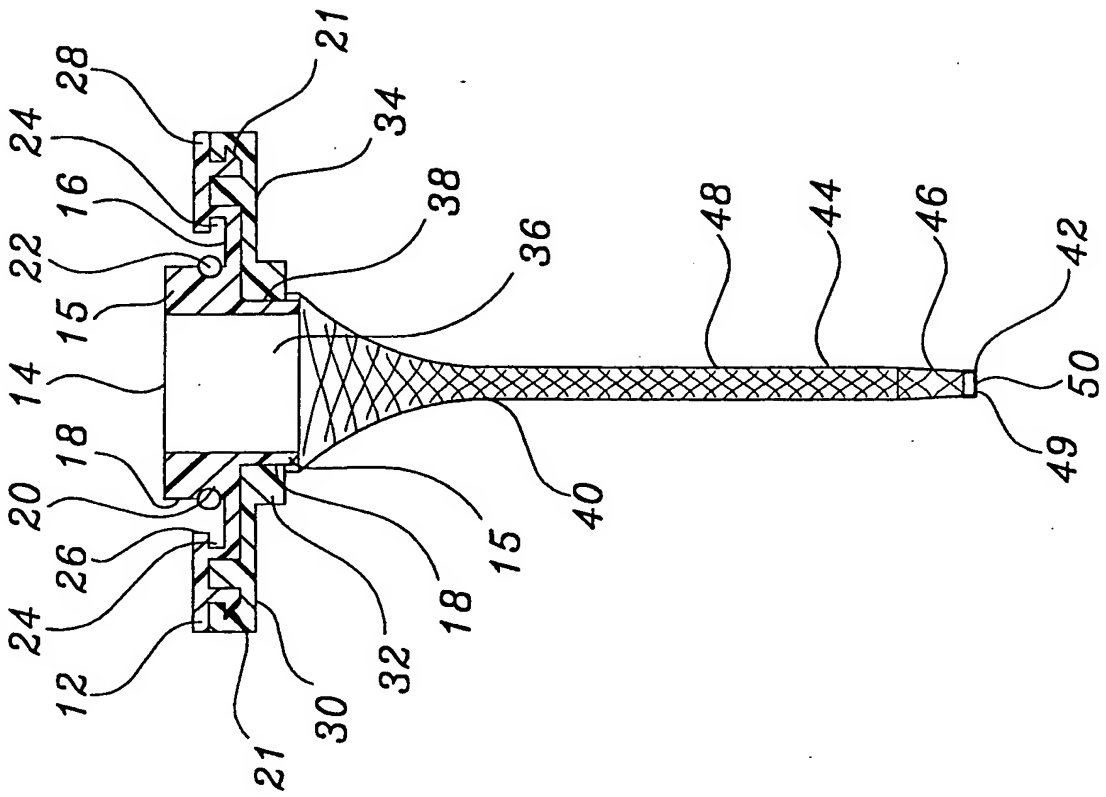

Figure 9

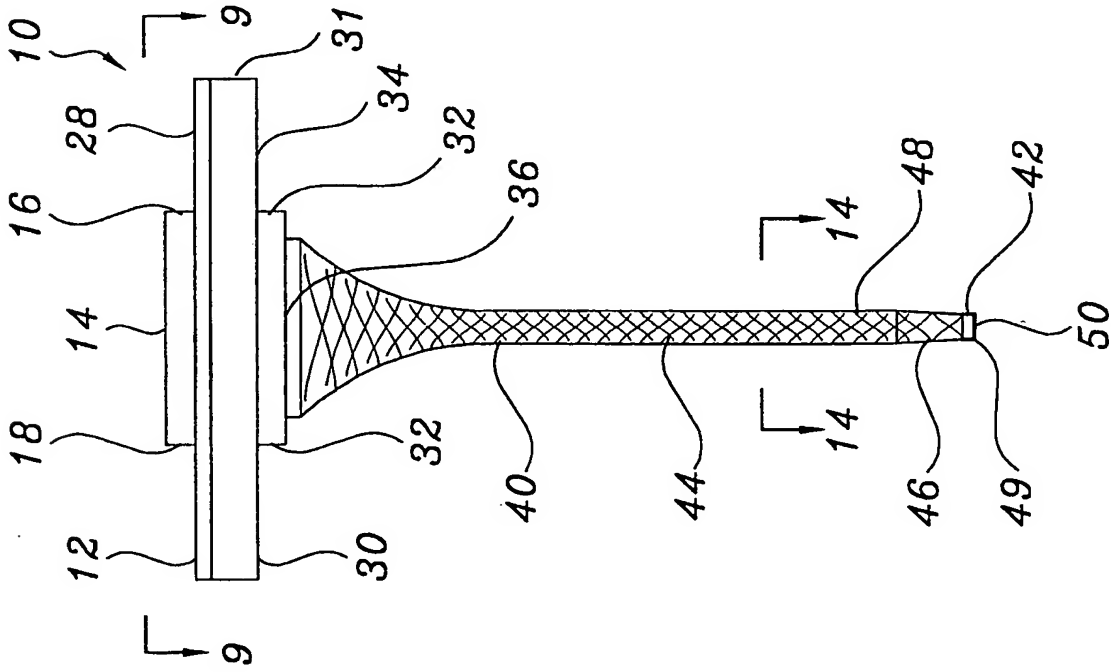

Figure 1

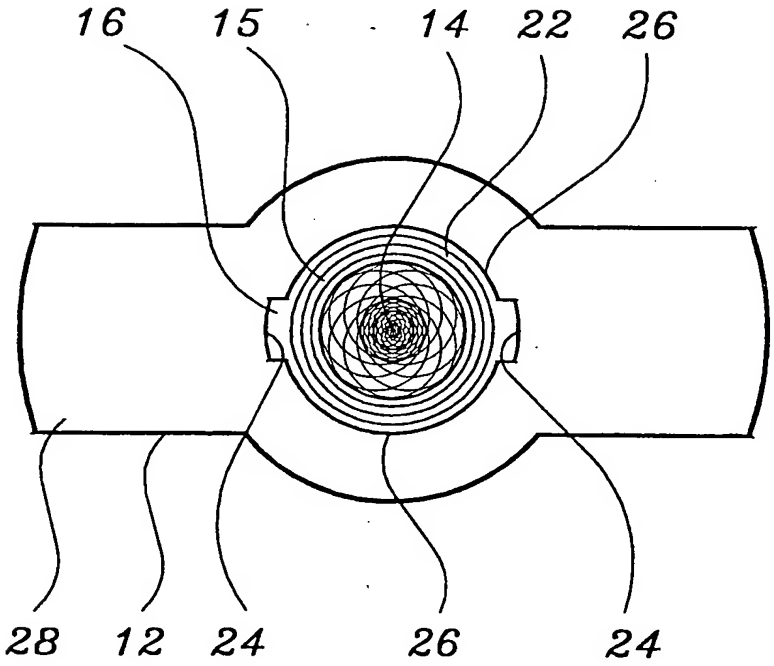

Figure 2

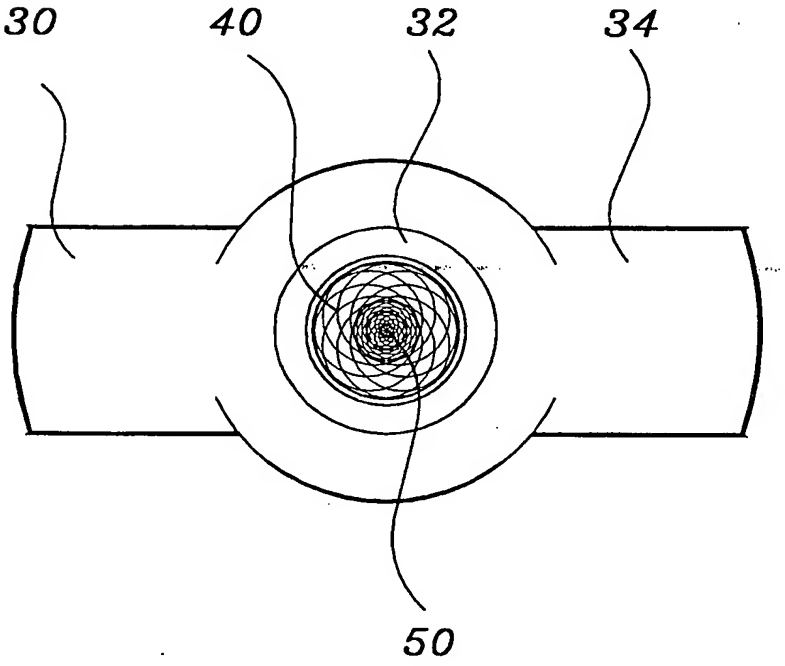

Figure 3

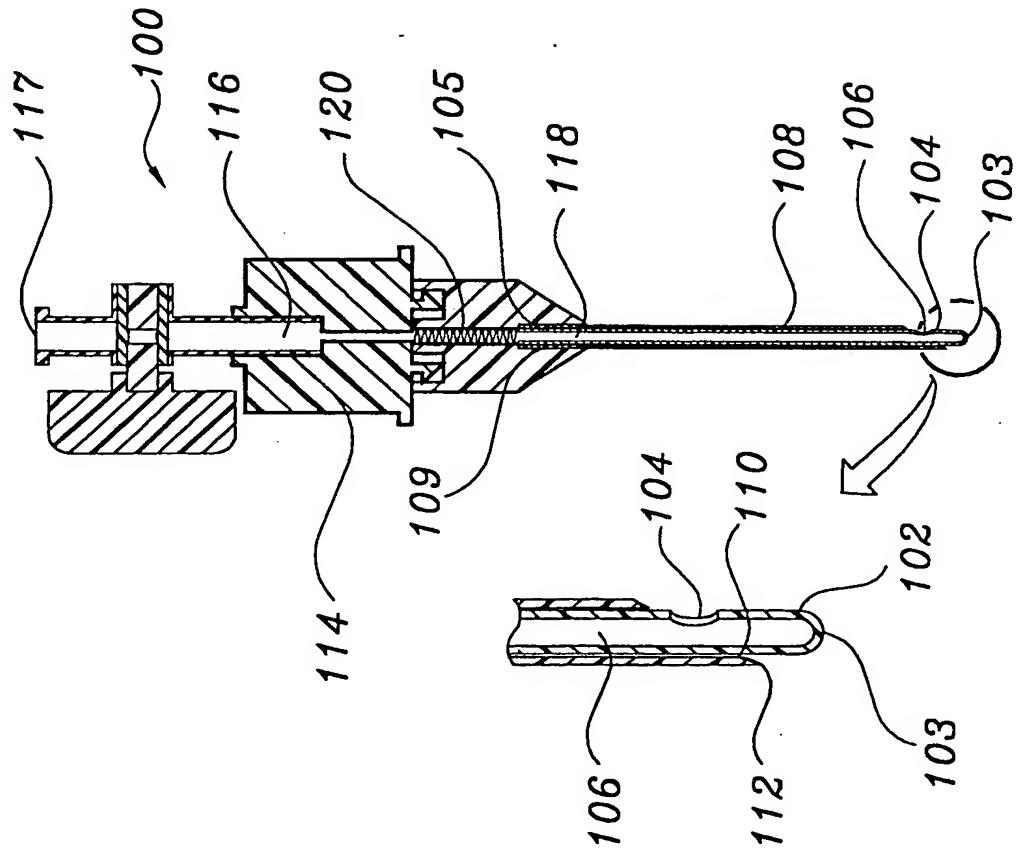

Figure 10

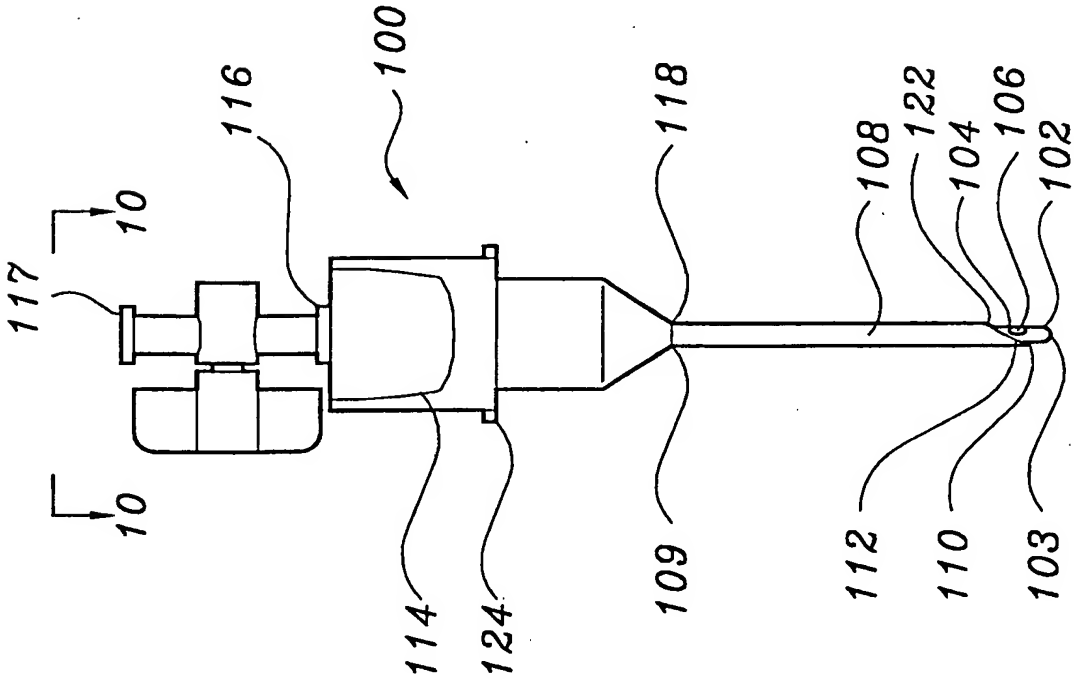

Figure 4

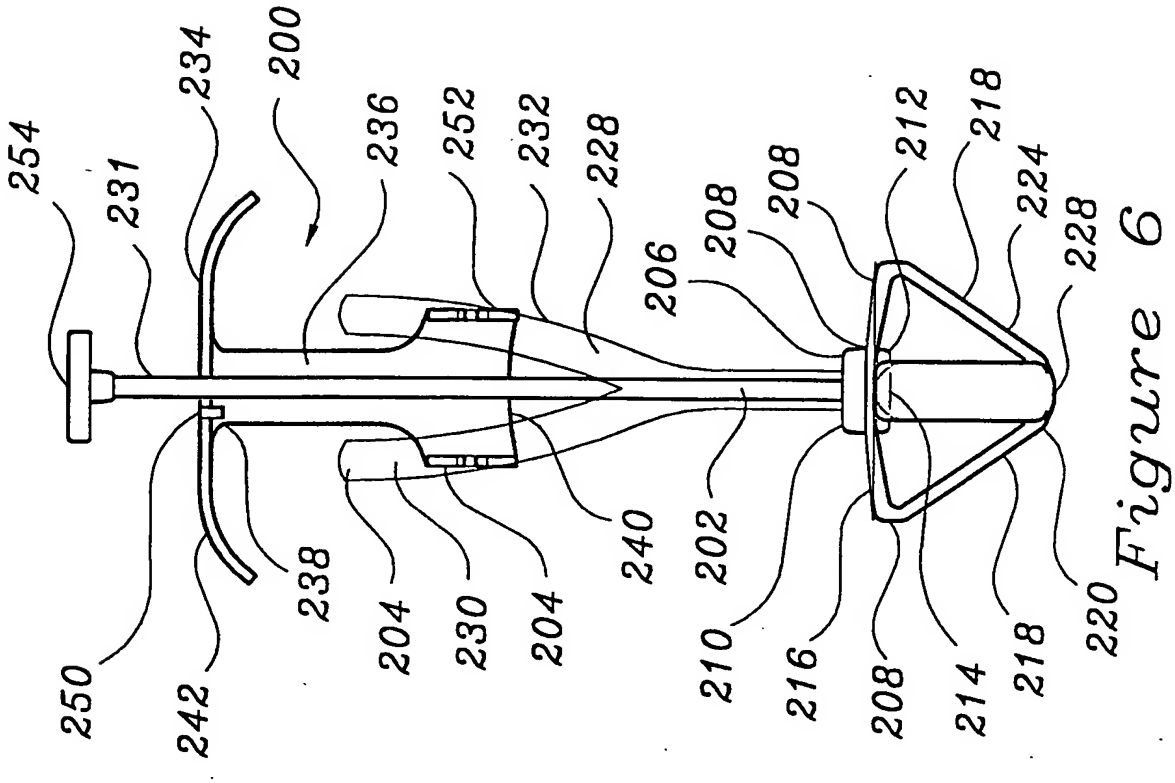

Figure 6

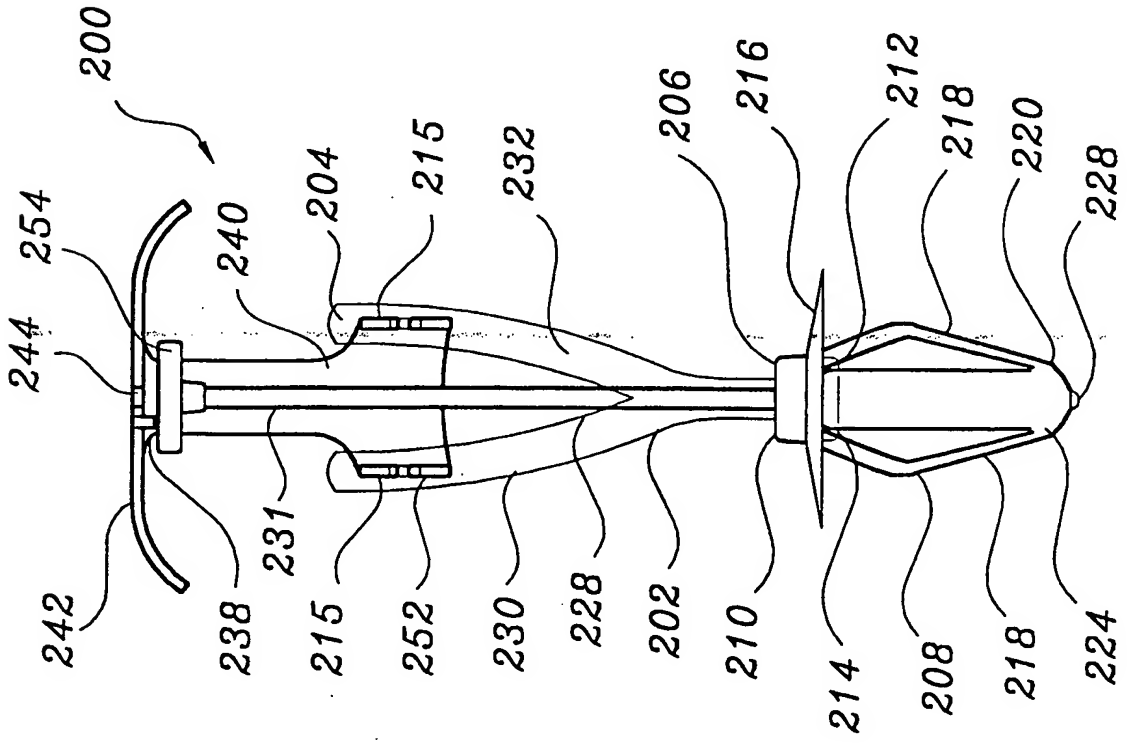

Figure 5

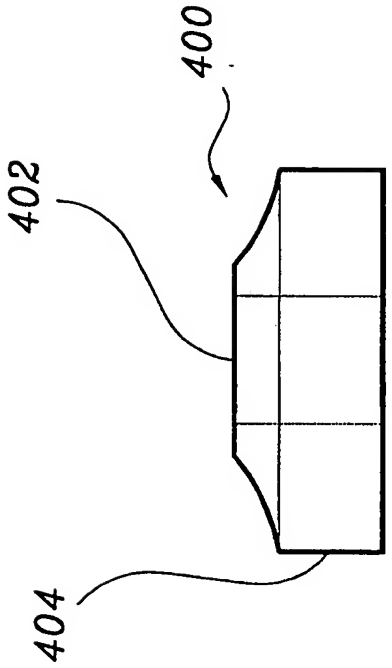

Figure 8

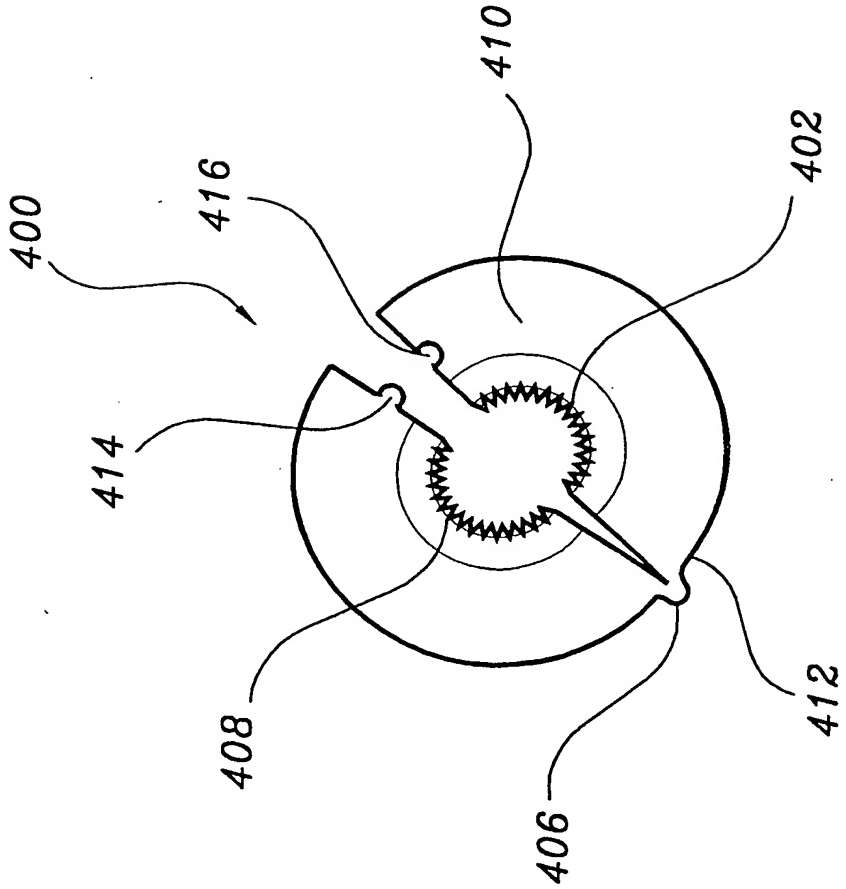

Figure 7

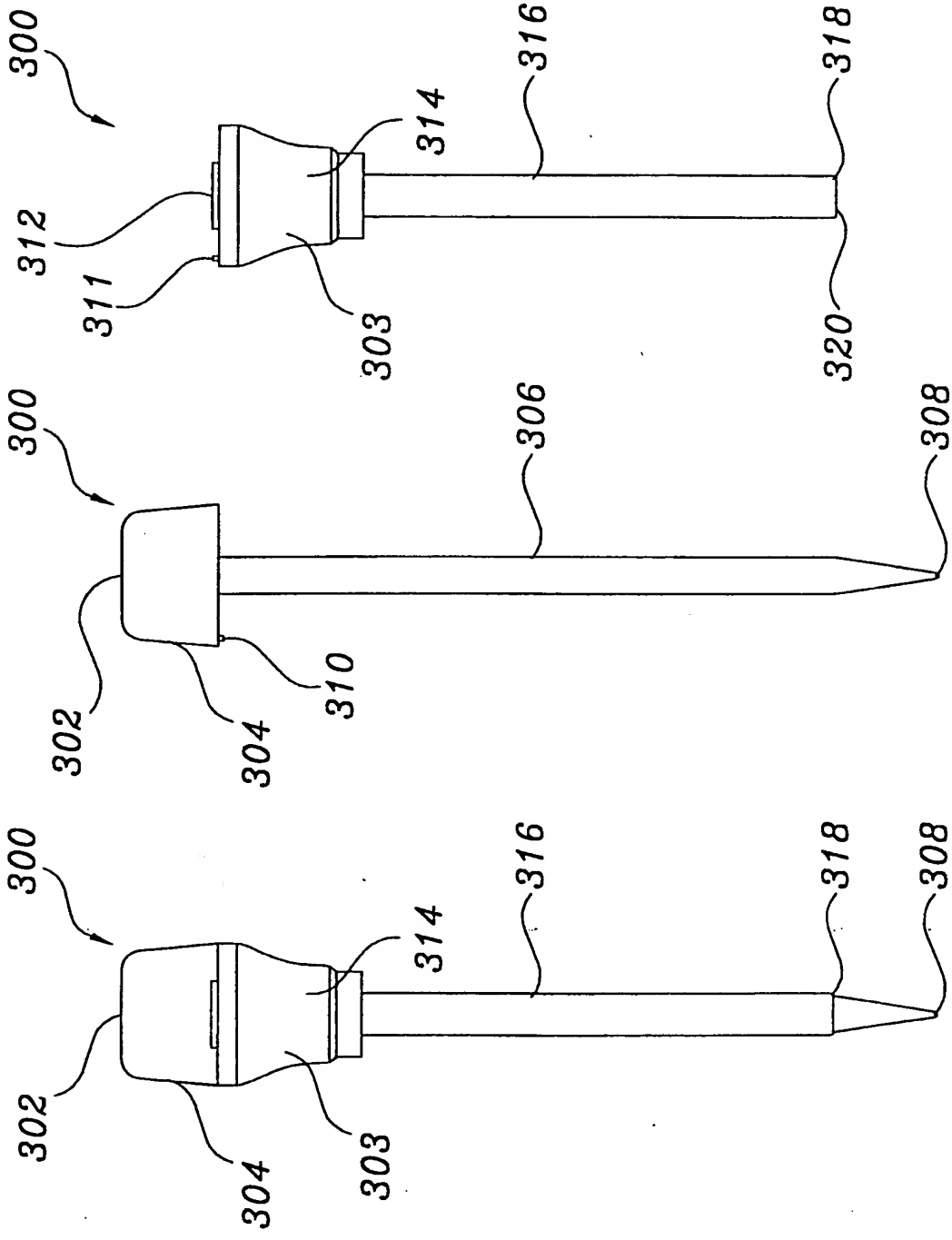

Figure 11 Figure 12 Figure 13

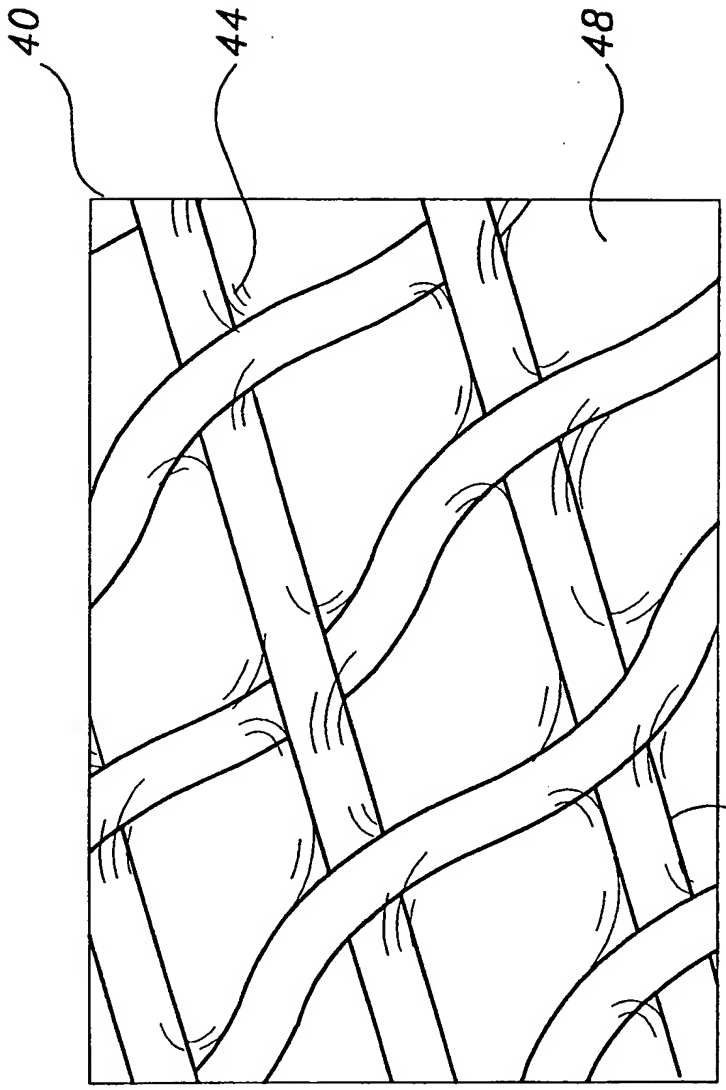

Figure 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/19395

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 25/00, 29/00
US CL :604/105, 164; 606/108, 198
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96, 104, 105, 164; 606/108, 198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS
Search Terms: expandable, dilator, coating, teflon, dilation, bolster

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,397,699 A (KOHL) 20 August 1968, col. 3 line 60 to col. 4 line 15, and Figs. 1 and 2.	6, 11-13
Y	US 4,154,242, A (TERMANINI) 15 May 1979, Figs. 1 and 2.	6, 11, 13
Y	US 4,487,808 A (LAMBERT) 11 December 1984, whole document.	2, 3
Y	US 5,112,310 A (GROBE) 12 May 1992, Figs. 7C-7E.	4, 11
X	US 5,454,790 A (DUBRUL) 03 October 1995, Figs. 1-3 and 17-24.	1, 5, 6, 8
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Y		2-4, 11-13

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 20 JANUARY 1998	Date of mailing of the international search report 19 FEB 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JULIAN W. WOO Telephone No. (703) 308-0421

Form PCT/ISA/210 (second sheet)(July 1992)★

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/19395

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,460,170 A (HAMMERSLAG) 24 October 1995, Figs. 3 and 4.	1 --- 2, 3, 12